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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,057	07/11/2001	K. Roger Aoki	16952CON1DIV8DIV5	3069

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EXAMINER	
AUDET, MAURY A	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,057	AOKI ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2, 3, & 5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statements

The Information Disclosure Statements of Paper No.'s 2, 3, and 5 have been considered. An initialed copy of Form PTO-1449 in accordance with MPEP § 609 is attached.

Requirement for Information

An issue as to the contents of PCT Form 210, of PCT/US94/14717 has been raised in this application. PCT/US94/14717 is a continuation of 08173996, which the present application also claims priority. The PCT/US94/14717 application file could not be located, and a search/printout of the publication of PCT/US94/14717 revealed that the Form 210 was not published with the application. In order for the Examiner to properly consider patentability of the claimed invention, a copy Form 210 is required, so that the Examiner may consider the prior art made of record in PCT/US94/14717. Applicant is required to include a copy of Form 210 in response to the present action.

Applicant is reminded that failure to fully reply to this requirement for information will result in a holding of abandonment.

Rejections

35 U.S.C. § 112, 2nd ¶

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23, and 27-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 23, 27, 30, and 31, the invention is drawn to a method for treating a muscle spasm, wherein the administration of the botulinum toxin type B results in an alleviation of the muscle spasm within 1 day to about 7 days. It is unclear what the maximum alleviation time due to the use of the term "about". It was not found in the specification where this maximum timeframe (i.e. day) is described. Applicant must point out where in the specification such a description may be found; or distinctly claim the alleviation timeframe so that it can be determined how much time "about" is meant to encompass; or delete the term "about".

35 U.S.C. § 102: Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-25, and 27-28 are rejected under § 102 (b), as anticipated by Harris et al.. (US 5482931).

Johnson et al. teach the use of botulinum type B for treatment of "muscle spasms" (column 2, lines 44-45 and 65-66), such as blepharospasm (column 1, line 45).

Therefore, the reference is deemed to anticipate the instant claims above.

35 U.S.C. § 103 Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. in view of Elston et al. (1985, Br J Opthalmol); further in view of Borodic et al. (1993, Ophthal Plast Reconstr Surg) or Schantz et al. (1992, Microbiological Reviews) or Wilson et al. (1982; Pediatr Infect Dis).

The teachings of Johnson et al. are discussed above. Johnson et al. teach the use of botulinum type B for muscle spasms, and teach in the specification that blepharospasm is one of the disorders within the broad class of muscle spasms. Johnson et al. does not specifically teach "strabismus" as one of the "muscle spasm". [Applicant's claims 26, 29-31]

Elston et al. teach successful treatment of strabismus with Botulinum toxin type A by injection (abstract; and as cited in US 6290961 at column 1, lines 42-43). Elston et al. does not specifically teach the units of administration to achieve successful treatment or the days of alleviation.

Borodic et al. teach botulinum B toxin as an alternative to botulinum A toxin since type B produces pharmacologic effects on innervation of striated muscle similar to type A (abstract, as cited in IDS, Paper No. 5). More importantly, Borodic et al. teach that immunologic tolerance has been demonstrated after therapeutic botulinum A toxin injections, implicating type B as a likely candidate for replacement therapy in those who have developed immunologic tolerance to type A (abstract).

Schantz et al., like Borodic et al., also teach that "[t]ypes of botulinum [i.e. B] other than type A toxin . . . may be useful for human treatment if patients develop immunity to type A toxin (page 93, "Conclusion", last ¶; as cited in IDS, Paper No. 5).

Wilson et al. teach that "extraocular muscle paralysis, dilated pupils . . . occurred significantly more frequently among infants with type B botulism than among those with type A botulism" (abstract), indicating that type B would likely serve to reduce muscle spasm with greater potency than type A, if used for such treatments.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use botulinum type B as taught by Borodic et al., Schantz et al., or Wilson et al., further in view of Elston et al., to treat strabismus in the method of treatment using botulinum type B of Johnson et al.; because either Borodic et al. or Schantz et al. teach that it would be advantageous to use botulinum type B in the treatment of muscle fibers (i.e. spasms such as blepharospasm and/or strabismus) when type A immunologic tolerance has developed in a patient; or because Borodic et al. teach that type B may work as effectively on striated muscle as type B (wherein shortages or impurities of type A would warrant the use of type B); or because Wilson et al. teach that clinical results in humans show that type B can reduce muscle spasm with greater potency than type A; and further in view of Elston et al.'s likewise treatment of strabismus, another type of "muscle spasm" with botulinum type A. Determination of the units of administration to achieve successful treatment (i.e. namely, less than that capable of producing botulism symptoms and determining the days of alleviation, are well within the skill of one in the art, as shown by the successful treatment of "muscle spasm" using botulinum type B by Johnson et al.)

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elston et al. (1985, Br J Opthalmol) in view of Borodic et al. (1993, Ophthal Plast Reconstr Surg) or Schantz et al. (1992, Microbiological Reviews) or Wilson et al. (1982; Pediatr Infect Dis); further in view of. Adenis et al. (1990, J Fr Ophthalmol).

Elston et al. teach successful treatment of strabismus with Botulinum toxin type A by injection (abstract; and as cited in US 6290961 at column 1, lines 42-43). Elston et al. does not specifically teach the units of administration to achieve successful treatment or the days of alleviation.

Borodic et al. (1993, Ophthal Plast Reconstr Surg), Schantz et al. (1992, Microbiological Reviews), and Wilson et al. (1982; Pediatr Infect Dis) are all discussed above.

Adenis et al. teach successful treatment of blepharospasm with botulinum toxin type A by injection (abstract; and as cited in US 6290961 at column 1, lines 43-44).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use botulinum type B as taught by Borodic et al., Schantz et al., or Wilson et al., further in view of Adenis et al., to treat strabismus and/or blepharospasm of Elston et al.; because either Borodic et al. or Schantz et al. teach that it would be advantageous to use

botulinum type B in the treatment of muscle fibers (i.e. spasms such as blepharospasm and/or strabismus) when type A immunologic tolerance has developed in a patient; or because Borodic et al. teach that type B may work as effectively on striated muscle as type B (wherein shortages or impurities of type A would warrant the use of type B); or because Wilson et al. teach that clinical results in humans show that type B can reduce muscle spasm with greater potency than type A; and further in view of Adenis et al.'s likewise treatment of blepharospasm with botulinum type A. Determination of the units of administration to achieve successful treatment (i.e. namely, less than that capable of producing botulism symptoms and determining the days of alleviation, are well within the skill of one in the art, as shown by the successful treatment of strabismus by Elston et al.)

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adenis et al. (1985, Br J Opthalmol) in view of Borodic et al. (1993, Ophthal Plast Reconstr Surg) or Schantz et al. (1992, Microbiological Reviews) or Wilson et al. (1982; Pediatr Infect Dis); further in view of Elston et al. (1990, J Fr Ophthalmol);

Adenis et al. teach successful treatment of blepharospasm with botulinum toxin type A by injection (abstract; and as cited in US 6290961 at column 1, lines 43-44). Adenis et al. does not

specifically teach the units of administration to achieve successful treatment or the days of alleviation.

Borodic et al. (1993, Ophthal Plast Reconstr Surg), Schantz et al. (1992, Microbiological Reviews), Wilson et al. (1982; Pediatr Infect Dis), Adenis et al, and Elston et al. are all discussed above.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use botulinum type B as taught by Borodic et al., Schantz et al., or Wilson et al., further in view of Elston et al., to treat strabismus and/or blepharospasm of Adenis et al.; because either Borodic et al. or Schantz et al. teach that it would be advantageous to use botulinum type B in the treatment of muscle fibers (i.e. spasms such as blepharospasm and/or strabismus) when type A immunologic tolerance has developed in a patient; or because Borodic et al. teach that type B may work as effectively on striated muscle as type B (wherein shortages or impurities of type A would warrant the use of type B); or because Wilson et al. teach that clinical results in humans show that type B can reduce muscle spasm with greater potency than type A; and further in view of Elston et al.'s likewise treatment of strabismus with botulinum type A. Determination of the units of administration to achieve successful treatment (i.e. namely, less than that capable of producing botulism symptoms and determining the days of alleviation, are well within the skill of one in the art, as shown by the successful treatment of blepharospasm by Adenis et al.)

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at

the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-31 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6290961 (Aoki et al.) in view of Elston et al. (1985, Br J Opthalmol) and Adenis et al. (1990, J Fr Ophthalmol); further in view of Borodic et al. (1993, Ophthal Plast Reconstr Surg) or Schantz et al. (1992, Microbiological Reviews) or Wilson et al. (1982; Pediatr Infect Dis).

Claims 1-8 of US '961 are drawn to a method for treating cervical dystonia (a disorder m marked by muscle spasms), which include all the other respective limitations of the instantly claimed invention, other than specifically treating blepharospasm and/or strabismus Namely, use of botulinum toxin type B, by intramuscular injection, with alleviation of cervical dystonia within 1 day to about 7 days, wherein the patient is administered at least 1,000 units of the botulinum toxin type B.

Borodic et al. (1993, Ophthal Plast Reconstr Surg), Schantz et al. (1992, Microbiological Reviews), Wilson et al. (1982; Pediatr Infect Dis), Adenis et al, and Elston et al. are all discussed above.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat blepharospasm and/or strabismus as taught by Adenis et al. and Elston et al. (using type A botulinum), further in view of Borodic et al., Schantz et al., or Wilson et al., in the claimed method of US '961 using type B botulinum; because either Borodic et al. or Schantz et al. teach that it would be advantageous to use botulinum type B in the treatment of muscle fibers (i.e. spasms such as blepharospasm and/or strabismus) when type A immunologic tolerance has developed in a patient; or because Borodic et al. teach that type B may work as effectively on striated muscle as type B (wherein shortages or impurities of type A would warrant the use of type B); or because Wilson et al. teach that clinical results in humans show that type B can reduce muscle spasm with greater potency than type A.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA
May 13, 2003

CHRISTOPHER R. TATE
PRIMARY EXAMINER